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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

FLYNN, AMANDA R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3751

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/839,643

Applicant(s)

KEREN ET AL.

Examiner

Amanda R. Flynn

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 12-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the left ventricle and the external signal activation for the check valve must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

2. The substitute specification filed on 13 November 2001 has been entered.
3. The abstract of the disclosure is objected to because the phrase "are disclosed" in line 3 can be implied from the specification and should be deleted. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 1 is unclear as to whether the "cardiac structure" is intended to be part of the claimed combination since positively claimed structure of the shunt is defined as being

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connected thereto (lines 2-3), but no positive structural antecedent basis therefore has been defined.

7. Claim 5 recites the limitation "said first portion" in line 2. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 10 recites the limitation "said tubular element" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Considering solely the subcombination, claims 1-2 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 4,705,507 to Boyles.

Regarding claims 1-2, Boyles shows an apparatus comprising a shunt. The Boyles shunt is capable of performing the functional elements of claims 1-2. The apparatus permits the shunting of a small volume of blood out of the left ventricle, thereby reducing the diastolic pressure of the heart (col. 3, lines 46-54). Regarding claim 11, the Boyles shunt can puncture a vessel wall when implanted in the cardiac structure.

11. Considering the combination, claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,429,144 to Wilk.

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Wilk discloses a stent (12) that is implanted in the cardiac structure of a patient (HW), and communicates between a first portion of the cardiac structure (LV) and an area outside the first portion (CA), to release a volume of blood from the first portion, and reduce pressure.

Regarding claim 11, the method of reducing pressure is anticipated by the normal use of the stent as disclosed by Wilk.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Considering solely the subcombination, claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyles.

Boyles discloses the previously described apparatus, further comprising a tubular element (11), as seen in Figure 1. Boyles lacks a teaching of an affixation element located at the ends of the tubular shunt.

The examiner takes official notice that a shunt must be affixed to a specific location in the cardiac structure, to ensure stability of the apparatus.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to produce the disclosed apparatus of Boyles, with affixation elements at its ends, to ensure stability and proper direction of blood flow through the device.

14. Considering solely the subcombination, claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyles in view of U.S. Patent Number 5,584,803 to Stevens et al.

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In regard to claims 3-4, Boyles discloses the previously described apparatus, further comprising a check valve (25) "which opens when the heart pumps and then closes thereby restricting blood flow when the heart relaxes (col.2, lines 63-65)," as seen in Figure 3. Boyles shows that the pumping and relaxing motions of the heart create a pressure differential, which allows passive functioning of the valve. Boyles lacks a teaching of preventing the shunting of blood during left ventricular systole, as claimed.

Stevens et al. disclose a system for cardiac procedures comprising a balloon catheter with a flexible tubular shaft, which is positioned adjacent the left ventricle. The shaft of the disclosed device "has a bending stiffness selected to maintain the position of the occluding means against systolic blood flow from the patient's heart when the occluding means is expanded (col. 9, lines 30-33)," thus preventing shunting during left ventricular systole.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to produce the disclosed arterial catheter of Boyles, with means of preventing left ventricular systole as described by Stevens et al., in order to reduce the end diastolic pressure.

***Allowable Subject Matter***

15. Claims 5-8 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

16. Claims 12-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda R. Flynn whose telephone number is 703-306-4056. The examiner can normally be reached on Monday-Thursday, 8:00 - 5:30 and alternate Fridays.

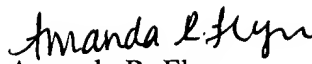
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory L. Huson can be reached on 703-308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

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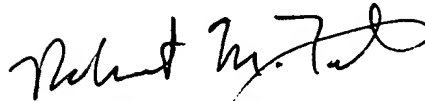
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Amanda R. Flynn  
Examiner  
Art Unit 3751

  
arf

January 14, 2003

  
ROBERT M. FETSUGA  
PRIMARY EXAMINER